European Medicines Agency

London, 13 December 2006
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

SUMMARY INFORMATION ON REFERRAL OPINION PURSUANT TO ARTICLE 30 OF COUNCIL DIRECTIVE 2001/83/EC FOR

Agopton and associated names (See Annex I)

International Non-Proprietary Name (INN): Lansoprazole

BACKGROUND INFORMATION

Agopton and associated names (lansoprazole) is a proton-pump inhibitor, which inhibits gastric acid secretion and therefore reduces the acid secretion of parietal cells. Lansoprazole is used for the treatment of diseases whose treatment is associated with the suppression of acid secretion in the stomach. Agopton and associated names is indicated for the treatment of peptic ulcers, reflux oesophagitis, and Zollinger-Ellison syndrome, the treatment and prophylaxis of NSAID-induced ulcers, and, in combination with antibiotics, for the eradication of *Helicobacter pylori*.

Agopton and associated names (lansoprazole) had been authorised via national procedures in 16 European Union Member States as well as in Iceland, Liechtenstein and Norway.
As a consequence of the national procedures the medicinal product did not have the same Summary of Product Characteristics (SPC) across the European Union Member States as well as in Iceland and Norway. This became obvious in mutual recognition procedures for other lansoprazole containing products in which the involved member states could not agree on the therapeutic indications and posology because the differences between the national authorisations of the reference product Agopton, Wyeth Lederle Nordiska AB.

The referral procedure started on 17 March 2005.
During its meeting on 18-21 September 2006 the CHMP, having considered the Rapporteur and the Co-Rapporteur assessment reports, the scientific discussion within the Committee and the comments from the Marketing Authorisation Holders (MAH), was of the opinion that the benefit/risk ratio of Agopton and associated names is considered to be positive for the following indications:

- Treatment of duodenal and gastric ulcer
- Treatment of reflux oesophagitis
- Prophylaxis of reflux oesophagitis
- Eradication of *Helicobacter pylori* (*H. pylori*) concurrently given with appropriate antibiotic therapy for treatment of *H. pylori* associated ulcers
- Treatment of NSAID-associated benign gastric and duodenal ulcers in patients requiring continued NSAID treatment
- Prophylaxis of NSAID-associated gastric ulcers and duodenal ulcers in patients at risk (see section 4.2) requiring continued therapy
- Symptomatic gastroesophageal reflux disease
- Zollinger-Ellison syndrome.

The divergences identified at the start of the referral were resolved.

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The CHMP gave a positive opinion on 21 September 2006 recommending the harmonisation of the SPC, labelling and package leaflet for Agopton and associated names.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II together with the amended SPC, labelling and package leaflet in Annex III.

A Decision was issued by the European Commission on 13 December 2006.